IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

GARY BRYAN BRACKIN, Individually and in his capacity as Surviving Spouse of PAMELA W. BRACKIN, Decreased Plaintiff v. MEDTRONIC, INC., and MEDTRONIC MINIMED, INC., Defendants	:	No. 2:17-cv-02101-SHL-cgc

PLAINTIFFS BRIEF IN SUPPORT OF OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF WILLIAM VIGILANTE, Ph.D.

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PRELIMINARY STATEMENT

Defendant seeks to exclude the testimony of plaintiff's human factors expert William Vigilante, Ph.D. largely on the basis that Dr. Vigilante "has zero experience or qualifications with respect to medical device labeling or warnings—the precise area addressed in his expert report." Defendant's Brief at 2. That argument fails, however, as Dr. Vigilante applied "basic human factors analysis" which "apply regardless of the system or the product whether it's a medical device, a vehicle, workplace equipment, consumer product et cetera . . . These are basic human factors principles and analysis techniques that are applicable to all system and product design." Deposition of William Vigilante,Ph.D., Defendant's Exhibit C at T174-6 to 174-16.

In this case Dr. Vigilante concluded that Medtronic's proprietary reservoirs and infusion sets were defective in design and for failure to warn. He concluded that had Medtronic conducted a proper human factors analysis during the design of the proprietary infusion set connector cap and associated reservoirs, it would have uncovered the hazard of insulin contaminating the reservoir and connector cap and could have designed the hazard out (as it did after the hazard was discovered in 2013) or provided a proper warning about the hazard and how to avoid it. Dr. Vigilante is not only qualified to render this opinion, but his opinion is fundamentally reliable.

LEGAL ARGUMENT

A. STANDARD FOR ADMISSION OF EXPERT OPINION

"In determining whether a witness is qualified to provide expert testimony, a district court must apply *Fed. R. Evid.* 702." *Bradley v. Ameristep*, 800 F.3d 205, 208 (6th Cir. 2015) (*citing United States v. Freeman*, 730 F.3d 590 (6th Cir. 2013)). Under Rule 702, a witness is qualified to offer expert testimony so long as he or she is "qualified as an expert by knowledge, skill, experience, training, or education." *Fed. R. Evid.* 702. If an expert is qualified to offer testimony,

the testimony must be admitted if "scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine the fact in issue; the testimony is based on sufficient facts or data; the testimony is the product of reliable principles and methods; and the expert has reliably applied the principles and methods to the facts of the case." *Id.*

Admissible expert testimony must be both reliable and relevant to the issues in a given case. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Relevant testimony "has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."

In *Lovelace v. Pediatric v. Anesthesiologists, P.A.*, 2014 U.S. Dist. LEXIS 182961 *2-3 (W.D. Tenn. Nov. 14, 2014), this court said, "[d]istrict courts have broad latitude in deciding whether to admit expert testimony under *Daubert."* (*citing United States v. Stafford*, 721 F.3d 380, 393 (6th Cir. 2013), *cert*. *denied*, 134 S. Ct. 463 (2013)). A district court's determination as to admissibility of expert testimony proceeds in three steps: "(1) 'the witness must be qualified,' (2) 'the testimony must be relevant,' and (3) 'the testimony must be reliable.' *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016), *reh'g en banc denied* (Sept. 27, 2016); *Berman v. Unimin Corp.*, 2016 WL 7240177 (W.D. Tenn. Dec. 14, 2016).

This court said in addition to the steps above, "'[a]n expert's proposed testimony must meet two additional requirements to be admissible: it must be (1) relevant, meaning that the testimony 'will help the trier of fact to understand the evidence or to determine a fact in issue,, and (2) reliable." *Lovelace*, 2014 U.S. Dist. LEXIS 182961 at *3 (*citing United States v. Cunningham*, 679 F.3d 355, 379-80 (6th Cir. 2012))

This court went on to state, "'[a]s gatekeeper, the trial court only determines the *admissibility* of expert evidence; the jury determines its weight. The court's focus is "solely on

principles and methodology, not on the conclusions that they generate."' *Id.* at *3 (*citing Stafford*, 721 F.3d at 394 (emphases added). "The essential role of *Daubert* is ensuring that the courtroom door remains closed to junk science, and therefore excluding relevant testimony of qualified medical experts in malpractice cases is rarely justified." *Id.* (*citing Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004))."

"Rejection of expert testimony is the exception, not the rule. *United States ex rel. Tenn. Valley Auth. v. 1.72 Acres of Land in Tenn.*, 821 F.3d 742, 749 (6th Cir. 2016). Any weakness in the underlying factual basis goes to the weight of the evidence, not its admissibility. *Daubert*, 509 U.S. at 596 ("vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). "Accordingly, Rule 702 should be broadly interpreted on the basis of whether the use of expert testimony will assist the trier of fact." *1.72 Acres of Land in Tenn.*, 821 F.3d at 749; *Berman*, 2016 U.S. Dist. LEXIS 172769, at * 9.

"Rule 702 'does not require anything approaching absolute certainty.' *Visteon Global Techs., Inc. v. Garmin Int'l, Inc.*, Case No. 10-cv-10578, 2016 WL 5956325, at *14 (E.D. Mich. Oct. 14, 2016) (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671-72 (6th Cir. 2010)). The court is not to determine whether the opinion is correct, but rather whether it 'rests upon a reliable foundation, as opposed to, say, unsupported speculation.' *Id.* (*quoting In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529-30 (6th Cir. 2008)). The accuracy of data underlying a reliable methodology normally goes to the weight of the opinion and not its admissibility." *Berman*, 2016 U.S. Dist. LEXIS 172769, at * 16

B. DR. VIGILANTE IS QUALIFED TO OFFER OPINIONS ON HUMAN FACTORS AS APPLIED IN THIS CASE

A witness is qualified to offer expert testimony so long as he or she is "qualified as an expert by knowledge, skill, experience, training, or education." F.R.E. 702. As the court in *Bradley, supra* observed: "[a]lthough a witness is not a qualified expert simply because he self-identifies as such, we take a liberal view of what 'knowledge, skill, experience, training, or education' is sufficient to satisfy the requirement. 800 F.3d at 208-09 (*quoting Pride v. BIC Corp.*, 218 F.3d 566 (6th Cir. 2000)).

Contrary to Medtronic's assertion, Plaintiff is not required to produce an expert who has human factors experience specific to medical devices. As Dr. Vigilante testified, the principles of human factors apply regardless of the system or the product whether it's a medical device, a vehicle, workplace equipment [or] consumer product . . . these are basic human factors principles and analyses that are applicable to all system and product design. Exhibit 3 at T174-6 to 174-20. *See, e.g., In re Yamaha Motor Corp. Rhino ATV Prod. Liab. Litig.*, 816 F.Supp.2d 442 (W.D. Ky. 2016) (expert with over 40 years of experience in the automotive industry qualified to opine on design failure modes and effects analysis (DFMEA) relating to an ATV even though the expert had no experience in the off-road industry).

In *In re Yamaha*, the court held that while the proffered expert's experience was entirely in the automotive industry, he was qualified to testify about DFMEA as applied to off-road vehicles because "these processes are not unique to that industry." *Id.* at 452. Indeed, the court noted that

> Yamaha has not shown why [Mr. Williams'] experience in the automotive industry is not transferable, particularly in light of Williams' admission that many of the standards he describes could be applied to products ranging from ATV's to toasters. To the extent Williams' lack of experience in this specific area is relevant, it can be inquired into on cross-examination.
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> *Id.*

The same holds true here. Dr. Vigilante is a human factors expert with "over 22 years of experience in the researching, designing, and evaluating . . . control-display design, consumer and commercial products and equipment, safety and hazard analyses, risk perception, and design of warnings and instructional materials." Exhibit 1. He has a Ph.D. from North Carolina State University in psychology/ergonomics and is board certified in professional ergonomics. *Id.* His doctoral dissertation involved "the presentation of risk and benefit information on direct-to-consumer advertisements of prescription medications on the web." He has authored or co-authored 29 "Technical Bulletins" on various aspects of human factors and usability analysis as well as textbook chapters on "Hazard Perceptions of Consumer Products," "Applying Usability Engineering Principles to the Design and Testing of Warning Text," "Attention Switch and Maintenance" and "Availability of Operator Manuals for Used Consumer Products." Journal articles include "Assessing risk and benefit communication in direct-to-consumer medication Web site advertising" (*Drug Information Journal*), "On the prioritization of safety warnings in product manuals" (*International Journal of Industrial Ergonomics*), "The preferred order of over-the-counter (OTC) pharmaceutical label components" (*Drug Information Journal*) and "Effects of label format on knowledge acquisition and perceived readability by younger and older adults" (*Ergonomics*). Exhibit 1 at 7-8.

Dr. Vigilante described human factors as

> [A]n applied science. And what I mean by that is that from a basic science standpoint, human factors professionals, researchers, conduct research, things related to, for example, how people gather information through their senses, through whether it's sight, hearing, tactile, etc. We look and study how people process information; that is, how they make decisions, how they store information into long-term memory, how information is transitioned into and out of short-term memory. We look at how people's experiences, their attitudes and beliefs, affect how they perceive risks and so forth

> We also look at what we call physical ergonomics; that is, how the body moves, muscles strength, flexibility. I think I mentioned human gait earlier in the deposition. So these are all different topics that from a basic standpoint human factors professionals study. We take that information that we learn through basic science and we apply it to the design of products and systems.
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> * * * * *
>
> So what we're trying to do is apply all of the stuff that we know about how people gather information, how they make decisions, the types of things that cause people to make mistakes or forget things. We take that information and we apply to design. And the goal is to design systems that are easy to use, that are comfortable to use and that are safe. Essentially, what we want to do is design for human use, and human use includes all of our abilities as well as all of our limitations. So I think that's a general description of the field of human factors.

Id. at 171-24 to 173-22.

The principles which underlie human factors analysis in the design of a product are not distinguished by product type but apply broadly to any product which will interact in one way or another with human beings. Dr. Vigilante is amply qualified by education, experience and training to offer opinions on issues of human factors and product defect in this case.

C. DR. VIGILANTE APPLIED A RELIABLE METHODOLOGY AND HIS OPINIONS ARE RELIABLE

.

In coming to his opinions, Dr. Vigilante focused his analysis on whether

- Medtronic's failure to conduct an adequate human factors analysis of its product was improper in a manner which caused or contributed to Pamela Brackin's injury and death.
- Medtronic provided adequate instructions and warnings with its Paradigm reservoir and infusion set regarding the hazard associated with the potential blockage of the P-cap connector vent.
- Medtronic's failure to provide adequate instruction and warning regarding the hazard associated with the potential blockage of its P-cap connector was improper in a manner which caused or contributed to Pamela Brackin's injury and death.

Exhibit 2 at 2.

Based upon his review of the history of the development of the P-cap and instructions for filling the reservoirs he concluded that Medtronic failed to conduct adequate human factors analysis and that the instructions and warnings the reservoirs were inadequate both in failing to contain any warnings or proper instructions to prevent the user from creating a hazard while filling the reservoirs. He approached this case

> from a product safety standpoint, a human factors standpoint, and came to my opinions based upon my training, my education and experience in the standard of care for a product design introducing a product into the market that's going to be used by the typical or average consumer such as the Brackins.

Exhibit 3 at T63-25 to 64-8.

And he applied the "same types of techniques and that same type of methodology in human factors that [he applies] in other types of products." Exhibit 3 at T174-6 to 175-4.

He noted in the first instance that the hazard uncovered in 2013 was foreseeable but not considered during the design of the P-cap because of a failure to do an adequate human factors analysis during the design process. Initially he faults Medtronic for failing to do a proper task analysis to understand the complexities associated with the reservoir filling technique and how that might result in the creation of a hazard. Vigilante Report, Exhibit 2 at 13

> There are multiple different tools and testing techniques other than usability studies [which is what Medtronic performed in the design of the P-cap and reservoirs] that human factors professionals utilize to assess the needs of users and the design of products including task analysis. However, at the heart of human factors analysis is task analysis. Task analysis is used to understand how people will use a product, the steps necessary to complete each task, and the tools and information necessary to complete each task . . . Task analysis is also used to identify the difficulty, error likelihood, and criticality for each step of the task.
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> *****
>
> Basic human factors principles and known user tendencies and expectations are considered in the analysis of each step. Basic human factors principles, tendencies, and expectations that should be assessed during the task analysis include:

- People prefer to use their dominant hand for tasks that require fine motor skills;
- Users prefer postures and positions that are comfortable and require the least amount of stress and/or force;
- People prefer to take the path of least resistance;
- People assume products are safe, do not look for unknown hazards, and therefore do not take proactive steps to avoid them;
- People expect objects to operate and move consistent with normal conventions (e.g., turn control clockwise to increase or turn on, turn counterclockwise to turn off or disengage;
- People lack knowledge about and experience with technological features (e.g. equalization of atmospheric pressure and its effect on vials);
- At times people are likely to forget, become distracted, or in a hurry; and
- People need adequate warnings and instructions to recognize and avoid non-open and obvious hazards.

To compensate for these human factors, product designers and manufacturers should:

- Consider the user's preferred hand when tasked with performing fine motor skills (e.g. manipulating small vials with their fingers);
- Design the tasks to eliminate undue muscle strain and stress;
- Simplify tasks and keep the number of steps to the required minimum;
- Ensure task controls, and products operate consistent with normal convention and stereotypes;
- Design the system to preclude misuse (i.e. cannot correctly complete task), ensure task continuity and pace (cannot perform task steps out of sequence), minimize the effects of error, and/or attract the user's attention to critical steps;
- Eliminate the hazard from the design of the system and if that is not possible include necessary safe guards to prevent injury; and
- Provide adequate warning and instruction to alert users to any residual hazard potential associated with the design of the system

Vigilante Report, Exhibit 2 at 12-13.

Applying these concepts to the reservoir filling process and P-cap connection, Dr. Vigilante observed that:

> With respect to the vent blockage hazard, task analysis would have revealed the potential for users to get liquid, including insulin, on the underside of the P-cap connector. For example, Medtronic and Unomedical provided IFU (information for use) instruction sheets with their Paradigm infusion set and reservoir. The reservoir IFU provides 10 steps for filling the reservoir and connecting it to the infusion set tubing via the P-cap connector. Contrary to basic human factors principles and guidelines for product design, a task analysis of the reservoir IFU reveals that users have to:
>
> 1. Swap the reservoir from their right hand on three occasions:

2. The user has to flip the orientation of the reservoir twice:

3. Assume a stressful shoulder posture:

4. Assume a posture contrary to normal convention:

5. Initiate a complex movement:

Id. at 13-14.

Vigilante observed that "a proper human factors analysis . . . would have also revealed that the natural way (consistent with movement expectancies, least stressful position, quickest, and the least steps) to perform the same task involves holding the reservoir in the dominant hand at a slight angle during each step of the process." *Id.* at 15. Significantly, he notes that "[t]he natural way to fill the reservoir and connect the P-cap is depicted in Medtronic's 'Create PrimeFill Anomaly video . . . [where] the user holds the reservoir, transfer guard, insulin vial combination at a slight angle with the reservoir below the insulin vial." *Id*. This was confirmed by a search of YouTube videos in which users purported to demonstrate the technique of filling the reservoir and connecting the infusion sets:

> The natural way to fill the reservoir and connect the P-cap is also depicted in videos of users. For example, I conducted an internet search for YouTube videos related to people using and instructing others on how to refill and connect a Minimed/Medtronic infusion set and reservoir using their proprietary P-cap connector. I was able to find 13 YouTube videos depicting non-medical professionals or Minimed/Medtronic sponsored product users. Of the 13 videos, seven depicted the user removing the reservoir from the transfer guard with the insulin vial still connected to the transfer guard and held above the reservoir. In one of these seven videos, the user instructs the viewer that she is going to depict the "proper" way of filling the reservoir and connecting the infusion set.

Exhibit 2 at 16.

Indeed, it is so natural that he notes that Medtronic's own engineer unwittingly made the very mistake of detaching the reservoir from the insulin vial without inverting them first:

> Based upon the task analysis it was also evident that the natural manner in which to remove the reservoir from the transfer guard can result in insulin dripping from the insulin vial due to its position above the reservoir and the increased pressure added to the vial during the insulin transfer step. For example, Mark Curtix, Medtronic certified validation engineer, "accidentally" recreated the problem when testing the infusion system to determine the root cause of the reported anomaly. Mark Curtis testified that when they were conducting their tests he noticed a drop of diluent (green solution with similar consistency of insulin used for testing [on the P-cap membrane]. ***Mark Curtis testified that he was shown how to fill the reservoir, had done it on one to two dozen prior occasions, had seen other people do it, knew how to do it correctly, and was trying to do it correctly. Even though he was trained, had seen others complete the steps, and had done it himself, Mark Curtis removed the reservoir (Step 6 in the reservoir IFU) from the transfer guard with the insulin above the reservoir. The naturalness of Curtis' action is also reflected in the fact that he did not understand how the green dot of diluent ended up on [the membrane] at first and had to think back what he might have done differently before figuring out he had the reservoir under the insulin vial when he removed it from the transfer guard.***
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> *Id.* at 16-17 (emphasis supplied).

But this "natural" way of removing the reservoir from the transfer guard while still below the insulin vial is potentially creates a hazard that the user might not recognize:

> The amount of insulin that may drop from the insulin vial is related to the amount of insulin left in the vial, the amount of air the user pumped into the vial in Step 2 of the reservoir IFU, and the angle at which the insulin vial is held in relation to the reservoir when the reservoir is removed. Therefore, the insulin may only drip out and onto the top of the reservoir as Mark Curtis described as opposed to squirting out as depicted in Medtronic's "Create PrimeFill Anomaly" video. Insulin is also clear and is more difficult to detect on the top of the reservoir compared to the green diluent. For example, Mark Curtis testified that had he been using insulin it would have been harder to see on the reservoir. ***A small amount of clear liquid on the top of the reservoir is likely to go unnoticed by the user when connecting the P-cap to the reservoir without adequate warning that the phenomenon can occur.***
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> *Id.* at 17 (emphasis supplied).

He concluded that

> Had Medtronic performed an adequate human factors analysis of their reservoir, infusion set, and P-cap connector they would have identified the potential for users to remove the reservoir while it was upright under the insulin vial, insulin to contaminate the P-cap membrane, and the hazard created by the blockage of the P-cap connector vents.

> Medtronic and failure to conduct an adequate human factors analysis of their reservoir, infusion set, and P-cap connector resulted in their failing to identify the hazard associated with the potential blockage of the P-cap vents prior to releasing the product for sale.
>
> Medtronic and Unomedical's failure to conduct an adequate human factors analysis was improper and unreasonably dangerous and created an unreasonably dangerous condition that caused or contributed to Rachel Dennert's injuries.

Id. at 15.

And this failure to identify the hazard through proper human factors analysis infected the instructions for use resulting in both inadequate instructions and no warnings. Despite the fact that the "Getting Started on Insulin" guide used to train the Brackins—which Mr. Brackin said her referred to maybe the first five or six times he did reservoir fills contains text describing the insulin vial as being "down" when disconnecting the reservoir from the transfer guard, Dr. Vigilante faulted it for failing to, among other things, inform the users of the hazard of failing to follow the instructions precisely:

> Instructions inform a user how to use the product properly and effectively. Warnings alert and inform the user of the hazards associated with the foreseeable use and misuse of the product, how to avoid the hazard, and the consequences for failing to avoid the hazard.
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> * * * * *
>
> Medtronic failed to provide adequate instructions and warning in its Getting Started guide regarding how to properly and safely fill the reservoir and connect it to the P-cap. And the potential of experiencing a P-cap vent block hazard. It was critical for Medtronic to provide adequate instructions and warnings it its Getting Started guide considering the natural tendencies (i.e. holding the insulin vial over the reservoir when disconnecting them) associated with the task and the potential for insulin to contaminate the top of the reservoir and transfer to the underside of the P-cap. It was also critical for Medtronic to provide adequate instructions and warnings in its Getting Started guide given the fact that its pump trainers were instructing people to rely on [it].

Id. at 18-19

In this case, in particular

Vigilante noted that "although the potential for users to get insulin on the underside of the P-cap connector and the hazard it created was foreseeable to the defendants, Medtronic and Unomedical failed to provide any warning to alert their product users to the"

- The importance of ensuring the reservoir is above the insulin vial when removing it from the transfer guard;
- The potential to get insulin on the top of the reservoir;
- The need to prevent insulin or other liquids from getting on the top of the reservoir or the underside of the P-cap;
- The hazard associated with getting insulin or any liquid on the underside of the P-cap connector;
- The need to ensure the top of the reservoir and underside of the P-cap are dry before connecting the two;
- The need to check to ensure the pump's slide screw is in contact with the reservoir plunger while priming; or
- The consequences of a blockage of the P-cap connector vents due to insulin or other liquids contaminating the underside of it.

Exhibit 2 at 20.

Dr. Vigilante concluded, among other things, that Medtronic's failure to identify the hazard through proper human factors analysis and design it out or provide adequate warnings if it chose not to design the hazard out resulted in a defective product which "created a unreasonably dangerous condition that caused or contributed to Pamela Brackin's injury and death. *Id.* at 24.

Here the expert applied standard human factors methodologies applicable to any product design to reach a reliable conclusion that Medtronic's product was defective in design and for failure to warn. There is no basis to exclude Dr. Vigilante's opinions or testimony and defendant's motion should be denied.

CONCLUSION

For the foregoing reasons, defendant's motion to exclude the testimony of Dr. Vigilante should be denied.

Respectfully submitted,

/s/ Kevin Haverty

Kevin Haverty, *pro hac vice*
WILLIAMS CEDAR LLC
8 Kings Highway West, Suite B
Haddonfield, NJ 08033
(856) 470-9777 (Tel)
Khaverty@williamscedar.com

Gary K. Smith, Esq.
R. Phillip Campbell, Esq.
GARY K. SMITH LAW, PLLC
FORUM III
1770 Kirby Parkway, Suite 427
Memphis, TN 38138
(901) 308-6484 (Tel)
(901) 308-6482 (Fax)
gsmith@garyksmithlaw.com
pcampbell@garyksmithlaw.com

CERTIFICATION OF SERVICE

This is to certify that I have this day served a copy of the within and foregoing **PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS MEDTRONIC, INC'S AND MEDTRONIC MINIMED, INC'S MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF MICHAEL KLIMOWICZ** via electronic mail to all counsel of record as follows:

Lori G. Cohen
GREENBERG TRAURIG, LLP
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, GA 30305
CohenL@gtlaw.com

Gary K. Smith
GARY K. SMITH LAW, PLLC
1770 Kirby Parkway, Suite 427
Memphis, TN 38138
gsmith@garyksmithlaw.com

Marlene J. Goldenberg
GoldenbergLaw, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
mjgoldenberg@goldenberglaw.com

This 28th day of September, 2018

/s/ Kevin Haverty
Kevin Haverty, *pro hac vice*
WILLIAMS CEDAR LLC
8 Kings Highway West, Suite B
Haddonfield, NJ 08033
(856) 470-9777 (Tel)
Khaverty@williamscedar.com